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Microbiota Restoration Therapy

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Rebiotix Completes Enrollment in Phase 2 Clinical Trial of New Drug for the Treatment of Recurrent *Clostridium difficile*-Associated Diarrhea

Trial is first multicenter study of next-generation fecal transplant

ROSEVILLE, Minn. (Jan. 13, 2014) — Rebiotix Inc. has announced that it has completed enrollment in the PUNCH™ CD Phase 2 clinical trial of RBX2660 (microbiota suspension) for the treatment of recurrent *Clostridium difficile*-associated diarrhea (CDAD). The study is the first of its kind prospective, multicenter clinical study to evaluate a non-antibiotic, live microbial drug product for the treatment of recurrent CDAD conducted using the same protocol at all sites.

A total of 40 patients at 13 centers across the United States were enrolled in the ground breaking study to assess the safety of RBX2660, an upgraded version of fecal transplant (FT) therapy. Secondary objectives of the study include gathering information on the efficacy and cost-effectiveness of the therapy.

“The investigators were very excited to use this product, and we are thrilled to be working with such a dedicated and professionally well-respected group of investigators”, said Rebiotix CEO Lee Jones. “Completion of enrollment in the study is a major milestone for the company and brings us that much closer to making this therapy widely available to patients suffering from this debilitating condition.”

Now that enrollment is complete, the study will continue until all follow-up data is collected.

The PUNCH™ CD study is the first prospective multicenter study of RBX2660, a new, non-antibiotic Microbiota Restoration Therapy (MRT) drug product that is a next generation FT therapy. The U.S. Food and Drug Administration (FDA) granted Fast Track status to the RBX2660 clinical program in May 2013 and approved the Phase 2 investigational new drug study in July 2013. The company is now working with the FDA to finalize the protocol for a randomized multicenter Phase 3 study of the drug.

Improving an Old Therapy

FT involving the human-to-human transfer of intestinal microbes in the form of fresh human feces has been used for over 50 years to treat recurrent *Clostridium difficile* (*C diff*) infection. Rebiotix leveraged the clinical proof of concept of FT and made improvements in its development of RBX2660. The labor intensive and cumbersome non-standardized donor screening and product preparation processes involved in FT have limited adoption of that therapy. RBX 2660, unlike FT, is a standardized, quality-controlled, ready- to-use product that has significant shelf life stability and has been tested in an FDA approved clinical study.

With RBX2660, Rebiotix is streamlining delivery of the therapy for both patients and physicians. “We want to make this therapy widely available and as easy to use as a flu vaccine,” Jones said.

Advancing the Science
Rebiotix is furthering evidence-based knowledge of microbiota restoration therapy (MRT) through a structured clinical research program. Documenting the safety and efficacy of RBX2660 not only strengthens evidence for the treatment of recurrent *C diff* infection but also sets the stage for use with other indications.

About *Clostridium difficile* Infection
C diff infection is a life-threatening intestinal infection that is usually hospital-acquired. It affects more than 700,000 people in the United States annually, placing an estimated $3 billion burden the healthcare system. Symptoms of *C diff* infection include profuse watery diarrhea and abdominal pain.

About Rebiotix
Rebiotix Inc. is a results-oriented biotechnology company revolutionizing the treatment of challenging gastrointestinal diseases by harnessing the power of the human microbiome. The Roseville, Minn.-based company is pioneering MRT to restore healthy gut flora through the transplantation of live microorganisms. For more information, visit www.Rebiotix.com.